



Billing Code: 4120-01-U-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS-367, CMS-10279, CMS-10483, CMS-301, CMS-317, CMS-319, CMS-10178 and CMS-10307]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS) is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: The necessity and utility of the proposed information collection for the proper performance of the agency's functions; the accuracy of the estimated burden; ways to enhance the quality, utility, and clarity of the information to be collected; and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. Type of Information Collection Request: Extension without change of a currently approved collection. Title of Information Collection: Medicaid Drug Program Monthly and Quarterly Drug Reporting Format; Use: Labelers transmit drug data to CMS within 30 days after the end of each calendar month and quarter. We calculate the unit rebate amount (URA) for each National Drug Code and distributes to all state Medicaid agencies. States use the URA to invoice the labeler for rebates. The monthly data is used to calculate Federal Upper Limit

prices for applicable drugs and for states that opt to use this data to establish their pharmacy reimbursement methodology. Form Number: CMS-367 (OCN: 0938-0578); Frequency: Monthly and quarterly; Affected Public: Private sector (business or other for-profits); Number of Respondents: 590; Total Annual Responses: 9,440; Total Annual Hours: 139,712. (For policy questions regarding this collection contact Cindy Bergin at 410-786-1176. For all other issues call 410-786-1326.)

2. Type of Information Collection Request: Reinstatement with change of a previously approved collection; Title of Information Collection: Ambulatory Surgical Center Conditions for Coverage; Use: The Ambulatory Surgical Center (ASC) Conditions for Coverage (CfCs) focus on a patient-centered, outcome-oriented, and transparent processes that promote quality patient care. The CfCs are designed to ensure that each facility has properly trained staff to provide the appropriate type and level of care for that facility and provide a safe physical environment for patients. The CfCs are used by federal or state surveyors as a basis for determining whether an ASC qualifies for approval or re-approval under Medicare. We, along with the healthcare industry, believe that the availability to the facility of the type of records and general content of records, which this regulation specifies, is standard medical practice and is necessary in order to ensure the well-being and safety of patients and professional treatment accountability. Form Number: CMS-10279 (OCN: 0938-1071); Frequency: Annual; Affected Public: Business or other for-profit, Not-for-profit institutions; Number of Respondents: 5,300; Total Annual Responses: 5,300; Total Annual Hours: 206,700. (For policy questions regarding this collection contact Jacqueline Leach at 410-786-4282. For all other issues call 410-786-1326.)

3. Type of Information Collection Request: New Collection (Request for a new control

number); Title of InformationCollection: Evaluation of the Multi-Payer Advanced Primary Care Practice (MAPCP) Demonstration: Conduct Beneficiary Experience with Care Surveys; Use: On September 16, 2009, the Department of Health and Human Services announced the establishment of the Multi-payer Advanced Primary Care Practice (MAPCP) Demonstration, under which Medicare joined Medicaid and private insurers as a payer participant in state-sponsored patient-centered medical home (PCMH) initiatives. We selected eight states to participate in this demonstration: Maine, Vermont, Rhode Island, New York, Pennsylvania, North Carolina, Michigan, and Minnesota.

We are conducting a survey to assess the care experiences of beneficiaries involved in the MAPCP Demonstration. We have chosen to measure patient experience using a validated, standardized survey questionnaire, the PCMH version of the Consumer Assessment of Healthcare Providers and Systems (PCMH-CAHPS). The PCMH-CAHPS is a validated, federally developed instrument that measures patient experience in 6 domains (access to care, provider communication, office staff interactions, attention to medical/emotional health, health care support, and medication decisions). Form Number: CMS-10483 (OCN: 0938-NEW); Frequency: Annually; Affected Public: Individuals and households; Number of Respondents: 10,038; Total Annual Responses: 10,038; Total Annual Hours: 3,313. (For policy questions regarding this collection contact Suzanne Goodwin at 410-786-0226. For all other issues call 410-786-1326.)

4. Type of Information Collection Request: Reinstatement of a previously approved collection; Title of Information Collection: Certification of Medicaid Eligibility Quality Control (MEQC) Payment Error Rates; Use: We conduct these to determine whether or not the sampled cases meet applicable state Title XIX or XXI eligibility requirements when applicable. The reviews are also used to assess beneficiary liability, if any, and to determine the amounts paid to

provide Medicaid services for these cases. In the Medicaid Eligibility Quality Control (MEQC) system, sampling is the only practical method of validating eligibility of the total caseload and determining the dollar value of eligibility liability errors. Any attempt to make such validations and determinations by reviewing every case would be an enormous and unwieldy undertaking. During each 6-month review period states are required to collect data on eligibility payment error dollars and paid claims dollars for each case in the sample. States must also identify cases for which a review cannot be conducted. At the conclusion of the 6-month review period, states must complete the Payment Error Rate form which contains aggregate data on sample size, number of sampled cases dropped, and number of sampled cases listed in error. These data, along with the calculated eligibility payment error rate and lower limit are certified by the State Medicaid Director (or designee) and submitted to the Regional Office. The collection of information is also necessary to implement provisions from the Children's Health Insurance Program Reauthorization Act of 2009 (CHIPRA) (Pub. L. 111-3) with regard to the MEQC and Payment Error Rate Measurement (PERM) programs. Form Number: CMS-301 (OCN: 0938-0246); Frequency: Semi-Annually; Affected Public: State, Local, or Tribal Governments; Number of Respondents: 51; Total Annual Responses: 102; Total Annual Hours: 16,446. (For policy questions regarding this collection contact Monetha Dockery at 410-786-0155. For all other issues call 410-786-1326.)

5. Type of Information Collection Request: Reinstatement of previously approved collection; Title of Information Collection: State Medicaid Eligibility Quality Control (MEQC) Sample Plans; Use: The Medicaid Eligibility Quality Control (MEQC) system is based on monthly state reviews of Medicaid and Medicaid expansion under Title XXI cases by states

performing the traditional sampling process identified through statistically reliable statewide samples of cases selected from the eligibility files. These reviews are conducted to determine whether or not the sampled cases meet applicable state Title XIX or XXI eligibility requirements when applicable. The reviews are also used to assess beneficiary liability, if any, and to determine the amounts paid to provide Medicaid services for these cases. In the MEQC system, sampling is the only practical method of validating eligibility of the total caseload and determining the dollar value of eligibility liability errors. Any attempt to make such validations and determinations by reviewing every case would be an enormous and unwieldy undertaking. In 1993, CMS implemented MEQC pilots in which states could focus on special studies, targeted populations, geographic areas or other forms of oversight with CMS approval. States must submit a sampling plan, or pilot proposal to be approved by CMS before implementing their pilot program. The Children's Health Insurance Program Reauthorization Act (CHIPRA) was enacted February 4, 2009. Sections 203 and 601 of the CHIPRA relate to MEQC. Section 203 of the CHIPRA establishes an error rate measurement with respect to the enrollment of children under the express lane eligibility option. The law directs states not to include children enrolled using the express lane eligibility option in data or samples used for purposes of complying with the MEQC requirements. Section 601 of the CHIPRA, among other things, requires a new final rule for the Payment Error Rate Measurement (PERM) program and aims to harmonize the PERM and MEQC programs and provides states with the option to apply PERM data resulting from its eligibility reviews for meeting MEQC requirements and vice versa, with certain conditions. CMS reviews, either directly or through its contractors, of the sampling plans helps to ensure states are using valid statistical methods for sample selection. The collection of

information is also necessary to implement provisions from the Children's Health Insurance Program Reauthorization Act of 2009 (CHIPRA) (Pub. L. 111-3) with regard to the MEQC and Payment Error Rate Measurement (PERM) programs. Form Number: CMS-317 (OCN: 0938-0148); Frequency: Semi-Annually Affected Public: State, Local, or Tribal Governments; Number of Respondents: 10; Total Annual Responses: 20; Total Annual Hours: 480. (For policy questions regarding this collection contact Monetha Dockery at 410-786-0155. For all other issues call 410-786-1326.)

6. Type of Information Collection Request: Reinstatement of a previously approved collection; Title of Information Collection: State Medicaid Eligibility Quality Control (MEQC) Sample Selection Lists; Use: The Medicaid Eligibility Quality Control MEQC system is based on monthly state reviews of Medicaid and Medicaid expansion under Title XXI cases by states performing the traditional sampling process identified through statistically reliable statewide samples of cases selected from the eligibility files. These reviews are conducted to determine whether or not the sampled cases meet applicable state Title XIX or XXI eligibility requirements when applicable. The reviews are also used to assess beneficiary liability, if any, and to determine the amounts paid to provide Medicaid services for these cases. In the MEQC system, sampling is the only practical method of validating eligibility of the total caseload and determining the dollar value of eligibility liability errors. Any attempt to make such validations and determinations by reviewing every case would be an enormous and unwieldy undertaking. At the beginning of each month, state agencies still performing the traditional sample are required to submit sample selection lists which identify all of the cases selected for review in the states' samples. The sample selection lists contain identifying information on Medicaid

beneficiaries such as: state agency review number, beneficiary's name and address, the name of the county where the beneficiary resides, Medicaid case number, etc. The submittal of the sample selection lists is necessary for regional office validation of state reviews. Without these lists, the integrity of the sampling results would be suspect and the regional offices would have no data on the adequacy of the states' monthly sample draw or review completion status. The authority for collecting this information is Section 1903(u) of the Social Security Act. The specific requirement for submitting sample selection lists is described in regulations at 42 CFR 431.814(h). Regional Office staff review the sample selection lists to determine that states are sampling a sufficient number of cases for review. Form Number: CMS-319 (OCN: 0938-0147); Frequency: Monthly; Affected Public: State, Local, or Tribal Governments; Number of Respondents: 10; Total Annual Responses: 120; Total Annual Hours: 960. (For policy questions regarding this collection contact Monetha Dockery at 410-786-0155. For all other issues call 410-786-1326.)

7. Type of Information Collection Request: Reinstatement of a previously approved collection; Title of Information Collection: Medicaid and Children's Health Insurance (CHIP) Managed Care Claims and Related Information; Use: The Payment Error Rate Measurement (PERM) program measures improper payments for Medicaid and the State Children's Health Insurance Program (SCHIP). The program was designed to comply with the Improper Payments Information Act (IPIA) of 2002 and the Office of Management and Budget (OMB) guidance. Although OMB guidance requires error rate measurement for SCHIP, 2009 SCHIP legislation temporarily suspended PERM measurement for this program and changed to Children's Health Insurance Program (CHIP) effective April 01, 2009. Please see Children's Health Insurance

Program Reauthorization Act of 2009 (CHIPRA) Public Law 111-3 for more details. There are two phases of the PERM program, the measurement phase and the corrective action phase. The PERM measures improper payments in Medicaid and CHIP and produces state and national-level error rates for each program. The error rates are based on reviews of Medicaid and CHIP fee-for-service (FFS) and managed care payments made in the federal fiscal year under review. States conduct eligibility reviews and report eligibility related payment error rates also used in the national error rate calculation. We created a 17 state rotation cycle so that each state will participate in PERM once every three years. Following is the list of states in which CMS will measure improper payments over the next three years in Medicaid. We need to collect capitation payment information from the selected states so that the federal contractor can draw a sample and review the managed care capitation payments. We will also collect state managed care contracts, rate schedules and updates to the contracts and rate schedules. This information will be used by the federal contractor when conducting the managed care claims reviews. Sections 1902(a)(6) and 2107(b)(1) of the Social Security Act grants CMS authority to collect information from the States. The IPIA requires CMS to produce national error rates in Medicaid and CHIP fee-for-service, including the managed care component. The state-specific Medicaid managed care and CHIP managed care error rates will be based on reviews of managed care capitation payments in each program and will be used to produce national Medicaid managed care and CHIP managed care error rates. Form Number: CMS-10178 (OCN: 0938-0994); Frequency: Occasionally; Affected Public: State, Local, or Tribal Governments; Number of Respondents: 34; Total Annual Responses: 2040; Total Annual Hours: 28,050. (For policy questions regarding this collection contact Monetha Dockery at 410-786-0155. For all other

issues call 410-786-1326.)

8. Type of Information Collection Request: Reinstatement with change of a previously approved information collection; Title of Information Collection: Medical Necessity and Claims Denial Disclosures under MHPAEA; Use: The Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA) (P.L.110-343) requires that group health plans and group health insurance issuers offering mental health or substance use disorder (MH/SUD) benefits in addition to medical and surgical (med/surg) benefits ensure that that they do not apply any more restrictive financial requirements (e.g., co-pays, deductibles) and/or treatment limitations (e.g., visit limits) to MH/SUD benefits than those requirements and/or limitations applied to substantially all med/surg benefits.

Medical Necessity Disclosure under MHPAEA

The MHPAEA section 512(b) specifically amends the Public Health Service (PHS) Act to require plan administrators or health insurance issuers to provide, upon request, the criteria for medical necessity determinations made with respect to MH/SUD benefits to current or potential participants, beneficiaries, or contracting providers. The interim final rules Under the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (75 FR 5410, February 2, 2010) set forth rules for providing criteria for medical necessity determinations. CMS oversees non-federal governmental plans or related health insurance.

Claims Denial Disclosure under MHPAEA

The MHPAEA section 512(b) specifically amends the Public Health Service (PHS) Act to require plan administrators or health insurance issuers to supply, upon request, the reason for any denial of payment for MH/SUD services to the participant or beneficiary involved in the case.

The interim final rules Under the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (75 FR 5410, February 2, 2010) implement 45 CFR 146.136(d)(2), which sets forth rules for providing reasons for denial of payment. We oversee non-federal governmental plans or related health insurance, and the regulation provides a safe harbor such that plans or issuers are deemed to comply with requirements of paragraph (d)(2) of 45 CFR 166.136 if they provide the notice in a form and manner consistent with ERISA requirements found in 29 CFR 2560.503-1. Form Number: CMS-10307 (OMB Control No. 0938-1080); Frequency: On Occasion; Affected Public: State, Local, or Tribal Governments; Number of Respondents: 20,300; Number of Responses: 509,600; Total Annual Hours: 2,200. (For policy questions regarding this collection, contact Usree Bandyopadhyay at 410-786-6650. For all other issues call (410) 786-1326.)

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web Site address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>, or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov, or call the Reports Clearance Office on (410) 786-1326.

In commenting on the proposed information collections please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in one of the following ways by **[OFR—insert date 60 days after date of publication in the Federal Register]**:

1. Electronically. You may submit your comments electronically to <http://www.regulations.gov>. Follow the instructions for "Comment or Submission" or "More

Search Options" to find the information collection document(s) accepting comments.

2. By regular mail. You may mail written comments to the following address:

CMS, Office of Strategic Operations and Regulatory Affairs

Division of Regulations Development

Attention: Document Identifier/OMB Control Number _____

Room C4-26-05

7500 Security Boulevard

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Dated: May 28, 2013

Martique Jones

Deputy Director, Regulations Development Group

Office of Strategic Operations and Regulatory Affairs

[FR Doc. 2013-12950 Filed 05/30/2013 at 8:45 am; Publication

Date: 05/31/2013]